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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,817	09/26/2000	Joseph R. Byrum	38-21(51469)B	5384

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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,817	BYRUM ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The objection to the disclosure is withdrawn in light of the removal of the browser-executable codes.

Claim Rejections - 35 USC § 101

3. Claims 1 and 2 remain and claims 10-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well-established utility, for the reasons of record stated in the Office action mailed May 6, 2004. Applicants traverse the rejection in the papers filed August 6, 2004. Applicants' arguments have been fully considered as they apply to claims 1, 2, and new claims 10-15, but were not found persuasive.

Applicants argue that the Examiner supposedly acknowledged that the specification describes multiple utilities for the present invention (response, page 8, 1st and 2nd full paragraphs). However, the Examiner did not make any such acknowledgement. In the Office action mailed May 6, 2004, the Examiner merely provided a summary of what is written in the specification. The last Office action stated, on page 3 in the same location noted by Applicants in their response, that no particular use is disclosed for any putative protein encoded by SEQ ID NO: 4. Applicants argue that the nucleic acids of the invention are useful for determining the

presence or absence of polymorphisms, isolating specific promoter sequences, or to obtain nucleic acid homologues (response, page 8, 3rd full paragraph). However, the specification does not teach what the presence or absence of the polymorphism signifies, the identity of the specific promoter, or the function(s) of the nucleic acid homologues. Applicants attempt to draw an analogy between a microscope and the claimed nucleic acids, arguing that the nucleic acids may be used to identify and characterize nucleic acids in a sample, cell, or organism (response, page 9, 1st full paragraph). However, this is not a specific utility. Any nucleic acid may be used for this purpose. In the absence of the function of the claimed nucleic acids, there is no purpose to using them to identify and characterize nucleic acids in a sample, cell, or organism.

Applicants argue that the position, that utility is lacking because other nucleic acid molecules can be used for the same purpose, is wrong because there is not requirement of exclusive utility in patent law. Applicants cite the decision of *Carl Zeiss Stiftung v. Renshaw PLC* in support, for stating that an invention need not be the best or only way to accomplish a certain result (response, page 9, 2nd full paragraph). However, the Examiner has not stated that the invention needs to be the best or only way to accomplish a certain result. The specification does not teach what the certain result is for the utility of the instant invention. The specification does not teach what the substantial utility is of identifying polymorphisms, homologues, or other nucleic acids using the claimed nucleic acids.

Applicants argue that the claimed nucleic acids will identify a specific subset of related sequences, and that a random nucleic acid would not provide this supposedly specific utility. Applicants draw an analogy with a golf club, arguing that a golf club is designed to hit a ball in a manner that is distinct from other clubs (response, page 10, 1st full paragraph). However, the

specification does not identify the function or use of such a specific subset of nucleic acids. Therefore, this is not a "real world" context of use for the claimed nucleic acids. Further basic research is required to determine how to use the subset of nucleic acids identified by the claimed nucleic acids.

Applicants argue that the specification discloses that the claimed nucleic acids were isolated from cDNA libraries made from partially to fully open flower tissue of rice, and the specification describes methods to analyze the nucleic acids and their association with several different biological processes. Applicants assert that one of ordinary skill in the art would recognize that their utility is apparent without further research (response, paragraph bridging page 10-11). However, obviously further basic research is required to determine the real world use of the polymorphisms identified with the claimed nucleic acids. It is entirely unknown that polymorphisms would even be identified. Simply reciting a list of different biological processes, that the claimed nucleic acids may not even have anything to do with, does not fulfill the utility requirement.

Applicants argue that the rejection is improper because the Examiner has not assessed the credibility of the asserted utilities of the claimed invention (response, page 11, 1st full paragraph). However, credibility can only be assessed once at least one specific and substantial utility has been asserted. No such specific and substantial utility has been asserted, nor is any non-asserted utility obvious.

Claim Rejections - 35 USC § 112

4. Claims 1 and 2 remain and claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed May 6, 2004. Applicants traverse the rejection in the papers filed August 6, 2004. Applicants' arguments have been fully considered as they apply to claims 1, 2, and new claims 10-15, but were not found persuasive.

Regarding the rejection concerning the recitation, "substantially," Applicants argue that the term is understood by one skilled in the art particularly when read in light of the specification, and direct attention to page 16, lines 12-18 (response, page 12, 2nd and 3rd full paragraphs). This section of the specification indicates that the recitation, "substantially purified" refers to a molecule separated from substantially all other molecules normally associated with it in its native state. However, again, it remains unclear what is meant by the term "substantially." For example, when is a molecule considered to be "substantially" separated, as opposed to separated, or partially separated? This section of the specification also indicates that a substantially purified molecule may be greater than 60% free. However, the term, "may" is open language. It is does not exclude any other scenarios in which a molecule may be considered substantially purified.

Regarding the issue concerning the recitation, "or fragment thereof" in original claim 1: the amendment to claim 1 obviates this aspect of the rejection.

5. Claims 1-2 remain and new claims 10, 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed May 6, 2004. Applicants traverse the rejection in the papers filed August 6, 2004. Applicants' arguments have been fully considered as they apply to claims 1, 2, and new claims 10, 12-15, but were not found persuasive.

Applicants argue that the claims recite the required nucleic acid sequences percent sequence identities, and do not need to recite proteins (response, page 14, 1st full paragraph). However, the claims do not recite a function for the claimed nucleic acid molecules and, as such, encompass nucleic acid molecules that do not have the same functional activity as SEQ ID NO: 4. The specification does not describe any functional activity for SEQ ID NO: 4 and, therefore, does not correlate the functional activity of SEQ ID NO: 4 with the claimed genus of nucleic acid molecules. Applicants argue that if a person of ordinary skill would, after reading the specification, understand the inventor possessed the invention, even if not every nuance, then written description is met (response, paragraph bridging pages 14-15). However, Applicants have not correlated a single function with the claimed nucleic acid molecules. Further, the sequence of SEQ ID NO: 4 does not provide any information concerning the remaining sequences of the open reading frame in which it belongs. Applicants are not in possession of any such sequence.

Applicants argue that they have satisfied a test for written description in *Regents of University of California v. Eli Lilly and Co.*, by disclosing the nucleotide sequence of SEQ ID NO: 4 and variants thereof. Applicants argue that the sequence of SEQ ID NO: 4 and its

complement are shared by every member of the genus and distinguish them from non-members (response, paragraph bridging pages 15-16). However, the sequence of SEQ ID NO: 4 is not shared by every member of the claimed genus, as claims 12-15 encompass nucleic acid molecules that do not have the sequence set forth in SEQ ID NO: 4 or its complement. Applicants have not disclosed variants of SEQ ID NO: 4. Further, it is not clear what the functional significance of SEQ ID NO: 4 is to the remaining of the open reading frames to which it may belong. If SEQ ID NO: 4 does not encode a domain of importance, such as a catalytic domain or binding site, of the protein encoded by the open reading frame, then SEQ ID NO: 4 may be parts of unrelated nucleic acid molecules. This disclosed structural feature is not a substantial portion of the claimed genus of nucleic acid molecules.

6. Claims 1 and 2 remain and claims 10-15 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record stated in the Office action mailed May 6, 2004. Applicants traverse the rejection in the papers filed August 6, 2004. Applicants' arguments have been fully considered as they apply to claims 1, 2 and new claims 10-15, but were not found persuasive.

Applicants argue that the rejection is overcome by the foregoing arguments regarding utility (response, page 16, 2nd full paragraph). However, as discussed above, Applicants' arguments were not found persuasive to overcome the utility rejection.

Applicants argue that an Applicant need not teach conventional and well-known genetic engineering techniques (response, page 17, 1st full paragraph). However, the Examiner has not required that well-known genetic engineering techniques be taught by Applicant. Applicants continue, arguing that an analysis of the Wands factors supports their position. Applicants argue that the first criterion, quantity of experimentation, is reduced by the extensive knowledge of, e.g., conservative nucleotide substitutions, identification of an active site, radiometric synthase assay conditions, to which a person of ordinary skill has access. Applicants argue that conducting sequences alignments, molecular weight determinations, and antibody hybridization assays, is not undue experimentation (response, page 17, 2nd full paragraph). However, the nucleotide sequence of the open reading frame to which SEQ ID NO: 4 belongs is unknown. It is not clear how, in the absence of that information, one cannot predict or identify an active site, or perform other assays. How one skilled in the art would use the information obtained from a radiometric synthase assay is not taught in the specification, nor is it obvious. It is also not unclear how one would use information gleaned from a molecular weight determination, or antibody when the function of the antigen that it binds is unknown. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicants assert that the second and third Wands criteria relate to the amount of direction or guidance and presence of working examples, and argue the specification provides percent sequence identity and how to isolate additional sequences in the genome (response, paragraph bridging pages 17-18). However, the specification provides no guidance at all in how one skilled in the art is to use such additional sequences.

Applicants assert that the fourth, fifth and sixth Wands criteria focus on the nature of the invention, state of the art, and relative skill in the art, and argue that the invention relates to nucleic acid sequences, that the specification describes amino acid sequences derived from them, antibodies, constructs, methods related thereto, and that practitioners of the art are guided by resources that can be used to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences (response, page 18, 1st full paragraph). However, the specification does not teach how one would use a transgenic host transformed with the claimed nucleic acid molecules. The specification does not teach how one skilled in the art would identify and confirm that a nucleic acid homologue has been isolated when the function of the open reading frame that SEQ ID NO: 4 belongs to has not been taught.

The seventh Wands criteria pertains to predictability of the art, and Applicants argue that the Examiner has not provide evidence why one skilled in the art would not be able to predict conservative substitutions or use the nucleic acid molecules in the disclosed uses (response, page 18, 2nd full paragraph). However, again, the specification does not teach how one skilled in the art would use any nucleic acid molecules that have been isolated using the claimed nucleic acid molecules, since the function of SEQ ID NO: 4 is unknown. What trait is conferred to a transgenic plant into which SEQ ID NO: 4 has been introduced, for example?

The eight criterion focuses on breadth of the claims, and Applicants argue that one of skill in the art is specifically guided by the disclosure to look to sequence identity to determine which species among those encompassed by the claimed genus possess the disclosed utility (response, paragraph bridging pages 18-19). However, one skilled in the art cannot make this

determination because the specification does not disclose a specific or substantial utility for the claimed invention, as discussed above.

Summary

7. Claims 1, 2, remain and 10-15 are rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 7, 2004

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Art Unit 1638